

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
COLUMBUS DIVISION

IN RE MENTOR CORP. OBTAPE	*	MDL Docket No. 2004
		4:08-MD-2004 (CDL)
TRANSOBTURATOR SLING PRODUCTS	*	
		Case No.
LIABILITY LITIGATION	*	4:11-cv-5073 (B. COLE)

O R D E R

Defendant Mentor Worldwide LLC developed a suburethral sling product called ObTape Transobturator Tape, which was used to treat women with stress urinary incontinence. Plaintiff Beryl Cole was implanted with ObTape, and she asserts that she suffered injuries caused by ObTape. Cole brought this product liability action against Mentor, contending that ObTape had design and/or manufacturing defects that proximately caused her injuries. Cole also asserts that Mentor did not adequately warn her physicians about the risks associated with ObTape.

Mentor seeks summary judgment on several of Cole's claims, including her claims for manufacturing defect, breach of implied warranty, breach of express warranty, fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation. Mentor also seeks summary judgment as to Cole's negligence claim to the extent it alleges a duty to recall and as to Cole's failure-to-warn claim to the extent she alleges that Mentor breached a continuing duty to warn. Mentor

does not seek summary judgment on the remainder of Cole's claims. As discussed in more detail below, Mentor's Motion for Partial Summary Judgment (ECF No. 83 in 4:11-cv-5073) is granted in part and denied in part. Cole agrees that her claims for breach of warranty and failure to recall should be dismissed, so the Court grants summary judgment as to those claims. The Court also grants summary judgment as to Cole's continuing duty to warn claim. Summary judgment is denied as to Cole's manufacturing defect claim and her claims for fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation.

SUMMARY JUDGMENT STANDARD

Summary judgment may be granted only "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In determining whether a *genuine* dispute of *material* fact exists to defeat a motion for summary judgment, the evidence is viewed in the light most favorable to the party opposing summary judgment, drawing all justifiable inferences in the opposing party's favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). A fact is *material* if it is relevant or necessary to the outcome of the suit. *Id.* at 248. A factual dispute is *genuine* if the evidence would allow a reasonable jury to return a verdict for the nonmoving party. *Id.*

FACTUAL BACKGROUND

Viewed in the light most favorable to Cole, the record reveals the following.

Cole is a Georgia resident, and all of her medical treatment relevant to this action occurred in Georgia. In 2004, Dr. George Mygatt diagnosed Cole with stress urinary incontinence. After discussing several options with Dr. Mygatt, Cole decided to undergo a transobturator sling procedure. Dr. Mygatt implanted Cole with ObTape on July 16, 2004. Dr. Bruce Kyburz assisted with the surgery. Cole did not speak with anyone from Mentor or see any brochures, videos, product inserts, or other materials from Mentor before the procedure.

Cole was initially happy with her ObTape implant and believed that her incontinence was cured. But in December 2010, Cole began experiencing a pain in her thighs. In January, she saw an orthopedic surgeon named Dr. Taylor Cates, who diagnosed Cole with a groin strain. Dr. Cates did not know at the time that Cole had been implanted with ObTape or that ObTape was associated with thigh abscesses. Cates Dep. 20:21-25, ECF No. 92-3. Dr. Cates testified that if he had known that Cole had been implanted with ObTape and that ObTape was associated with thigh abscesses, he would have "been more expedient in looking at OB-GYN[/]vaginal problems" and would have directed his

actions "more towards a solution to that problem versus a muscle problem or other issue." *Id.* 21:2-8, 16-22.

Cole's symptoms continued and then worsened in March 2011, when Cole experienced severe pain in her right leg, along with vaginal discharge. Cole visited the hospital again, and the hospital physician diagnosed Cole with an abscess due to an erosion of the ObTape. Shortly after that, Dr. Mygatt recommended removal of the ObTape, and in April 2011, Dr. Mygatt and Dr. Kyburz performed an excision surgery and removed as much of the ObTape as they could.

After Cole was implanted with ObTape but before she developed complications several years later, at least two of Dr. Kyburz's other ObTape patients developed abscesses. Kyburz Dep. vol. I 155:4-11, ECF No. 95-3; Kyburz Dep. vol. II 185:11-20, ECF No. 95-4. Based on his experience with those patients and his literature review, Dr. Kyburz determined that patients with infected ObTape needed to be treated differently than other patients with infected slings; if an ObTape patient developed an infection, then he would remove as much of the sling as possible. Kyburz Dep. vol. II 185:22-187:19. It is undisputed that if Cole presented to Dr. Kyburz today with an ObTape erosion and infection, he would treat her exactly the same as he did in 2011 by attempting to remove as much of the ObTape as possible. Despite what he learned about the risks of ObTape in

the years following Cole's implant surgery, Dr. Kyburz did not contact any of his ObTape patients regarding potential problems with ObTape. Kyburz Dep. vol. II 192:21-193:14.

Cole filed this action in the United States District Court for the Northern District of Georgia on September 13, 2011. See *generally* Compl., ECF No. 1 in 4:11-cv-5073. The action was later transferred to this Court as part of a multidistrict litigation proceeding regarding ObTape. Cole asserts claims against Mentor for negligence, design defect, manufacturing defect, failure to warn, breach of warranty, fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation.

DISCUSSION

The Judicial Panel on Multidistrict Litigation transferred this diversity action from the United States District Court for the Northern District of Georgia to this Court for pretrial proceedings. There is no question that Georgia law—the law of both the transferor court and the transferee court—applies.

I. Manufacturing Defect

Cole asserts that her ObTape had a manufacturing defect. A manufacturing defect is a defect that is measurable "against a built-in *objective* standard or norm of proper manufacture." *Banks v. ICI Ams., Inc.*, 264 Ga. 732, 734 n.2, 450 S.E.2d 671, 673 n.2 (1994) (quoting *Bowman v. Gen. Motors Corp.*, 427 F.

Supp. 234, 241 (E.D. Pa. 1977)); see also *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1348, 1365 (M.D. Ga. 2010) ("In manufacturing defect cases . . . the standard of comparison is supplied by the designer of the perfectly executed product that is in complete accordance with the intended design.") (quoting *Jones v. Amazing Prods., Inc.*, 231 F. Supp. 2d 1228, 1236 n.7 (N.D. Ga. 2002)). "Therefore, in a manufacturing defect case, the 'product's defectiveness is determined by measuring the product in question against the benchmark of the manufacturer's designs.'" *Id.* (quoting *ACE Fire Underwriters Ins. Co. v. ALC Controls, Inc.*, Civil Action No. 1:07-CV-606-TWT, 2008 WL 2229121, at *2 (N.D. Ga. May 28, 2008)).

Cole's claim for manufacturing defect is based on the same evidence that the Phase I Georgia Plaintiffs presented in opposition to summary judgment: evidence that (1) ObTape's product specifications called for pores measuring between 40 and 100 microns and (2) tests of ObTape samples revealed "non-uniform pores, some of which are closed-ended pores and the vast majority of which are smaller than 40 microns." *Id.* at 1376. Based on that evidence, the Court found a genuine fact dispute on the Phase I Georgia Plaintiffs' manufacturing defect claims. *Id.*

Mentor contends that Cole cannot make out a manufacturing defect claim because she did not point to any evidence that an expert examined the specific ObTape that was explanted from her body and opined that a manufacturing defect existed. But none of the Phase I Plaintiffs presented evidence that their specific ObTape was tested, either. *Id.* at 1376 n.11. Rather, they presented evidence that their experts had tested a number of ObTape samples and concluded that a substantial portion of each ObTape tested had pores smaller than 40 microns. *Id.* at 1376. Cole relies on that same evidence. Thus, for the reasons set forth in the Court's previous Order, the Court finds that genuine fact disputes exist on Cole's manufacturing defect claim. *See id.* at 1376-77.

II. Breach of Warranty

Cole agrees that summary judgment is appropriate on her breach of implied warranty and breach of express warranty claims, so the Court grants summary judgment on those claims.

III. Misrepresentation and Concealment Claims

Cole elected to undergo the ObTape procedure after consulting with Dr. Mygatt. She asserts that Dr. Mygatt received certain materials from Mentor that led him to recommend ObTape for Cole and that those materials contained material misrepresentations and concealed material facts about ObTape. Specifically, Cole contends that Mentor's representations to Dr.

Mygatt either misrepresented or concealed an accurate complication rate for ObTape, the severity of known ObTape complications, and true information about ObTape's physical characteristics. Cole's claims for fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation are based on these contentions.¹ All three claims require Cole to prove that she justifiably relied on a misrepresentation and that her reliance led her to suffer damages. See *UWork.com, Inc. v. Paragon Techs., Inc.*, 321 Ga. App. 584, 598, 740 S.E.2d 887, 898 (2013) (noting that "fraud has five elements: (1) a false representation or omission of a material fact; (2) scienter; (3) intention to induce the party claiming fraud to act or refrain from acting; (4) justifiable reliance; and (5) damages") (quoting *ReMax N. Atlanta v. Clark*, 244 Ga.App. 890, 893, 537 S.E.2d 138, 141 (2000)); see also *Anderson v. Atlanta Comm. for Olympic Games, Inc.*, 261 Ga. App. 895, 900, 584 S.E.2d 16, 21 (2003) (stating that "justifiable reliance is an essential element of a claim asserting negligent misrepresentation").

¹ It is the Court's understanding that Cole's fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation claims all relate to her claim that Mentor did not adequately warn her implanting physicians of the risks of ObTape *before her implant surgery*. To the extent Cole attempts to base her fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation claims on Mentor's alleged breach of its continuing duty to warn, those claims are barred for the same reasons her continuing duty to warn claim is barred: lack of causation.

Mentor contends that Cole cannot prove that she relied on any misrepresentation by Mentor because it is undisputed that Mentor did not make any representations directly to Cole. Rather, Mentor communicated exclusively with her physicians, Dr. Mygatt and Dr. Kyburz. In general, a fraudulent or negligent misrepresentation claim "must be based upon a misrepresentation made to the defrauded party, and relied upon by the defrauded party." *Fla. Rock & Tank Lines, Inc. v. Moore*, 258 Ga. 106, 106, 365 S.E.2d 836, 837 (1988) (emphasis omitted). But, "the requirement of reliance is satisfied where . . . A, having as his objective to defraud C, and knowing that C will rely upon B, fraudulently induces B to act in some manner on which C relies, and whereby A's purpose of defrauding C is accomplished." *Id.* at 107, 365 S.E.2d at 837. Here, Cole asserts that Mentor, intending to defraud her and induce her to undergo the ObTape procedure, made misrepresentations to Dr. Mygatt and induced him to recommend ObTape to Cole. Cole relied on Dr. Mygatt in deciding to proceed with the ObTape procedure. The Court is thus satisfied that a genuine fact dispute exists on the justifiable reliance element, and Mentor is not entitled to summary judgment on Cole's claims for fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation.

IV. Failure to Recall

Mentor moved for summary judgment on Cole's negligence claim to the extent it alleges that Mentor breached a duty to recall ObTape. Cole acknowledges that she may not pursue a failure to recall claim, so Mentor's summary judgment motion is granted as to this claim.

V. Continuing Duty to Warn

Cole contends that Mentor breached its continuing duty to warn her physicians of problems with ObTape and that she suffered damages as a result. To prevail on her claim, Cole must prove that if Mentor had provided an adequate post-implant warning, her doctors would have taken a different approach that would have prevented or mitigated her injuries. See *Porter v. Eli Lilly & Co.*, 291 F. App'x 963, 964 (11th Cir. 2008) (per curiam) (noting that the plaintiff had "to prove that, but for the alleged inadequate warning, [the decedent's physician] would not have prescribed Prozac to decedent").

Mentor argues that Cole did not point to sufficient evidence of causation on her continuing duty to warn claim because she did not point to evidence that either of her implanting physicians would have done anything differently had Mentor provided them with additional warnings regarding ObTape. Rather, the record establishes that Dr. Kyburz did not contact any of his patients after their implant surgeries even though he

learned of increased risks of ObTape. And if Cole presented to Dr. Kyburz today with the complications she had in 2011, Dr. Kyburz would treat her exactly the same as he did then.²

Cole did point to evidence that Dr. Cates, the orthopedic surgeon who diagnosed her with a strained groin in 2011, would have taken a different approach to her treatment had he known that (1) Cole had been implanted with ObTape and (2) ObTape was associated with thigh abscesses. Under Georgia law, the manufacturer of a medical device has a duty to provide warnings to "the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer." *McCombs v. Synthes (U.S.A.)*, 277 Ga. 252, 253, 587 S.E.2d 594, 595 (2003). "The rationale for the doctrine is that the treating physician is in a better position to warn the patient than the manufacturer, in that the 'decision to employ prescription [medical devices] involves professional assessment of medical risks in light of the physician's knowledge of a patient's particular need and susceptibilities.'" *Id.* (quoting *McCombs v. Synthes (U.S.A.)*, 250 Ga. App. 543, 545, 533 S.E.2d 17, 20 (2001)). Thus, while it is clear that Mentor had a duty to warn Cole's implanting physicians—Dr. Kyburz and Dr. Mygatt—of the risks associated

² Cole appears to argue that Mentor's summary judgment motion fails because Mentor did not establish what Dr. Mygatt would have done had Mentor given him additional warnings. But Cole has the burden to prove causation, so she must point to evidence that additional warnings would have changed the course of Dr. Mygatt's treatment after he implanted Cole with ObTape. She did not.

with ObTape, it is not clear that Mentor had a duty to warn all physicians everywhere of the risks of ObTape. Cole did not point the Court to any authority showing that Mentor had a duty to warn Dr. Cates, an orthopedic surgeon who does not make any decisions regarding the implant or explant of suburethral slings, and the Court found none. And, even if Georgia law did require Mentor to warn Dr. Cates of the risks associated with ObTape, there is no evidence that such a warning would have made a difference in Dr. Cates's treatment of Cole because Dr. Cates did not even know that Cole had been implanted with ObTape. For these reasons, Cole's continuing duty to warn claim fails.

CONCLUSION

As discussed above, Mentor's Motion for Partial Summary Judgment (ECF No. 86 in 4:11-cv-5073) is granted in part and denied in part. Summary judgment is granted as to Cole's claims for breach of express warranty, breach of implied warranty, failure to recall, and continuing duty to warn. Summary judgment is denied as to Cole's manufacturing defect claim and her claims for fraudulent misrepresentation, fraudulent concealment, and negligent misrepresentation.

IT IS SO ORDERED, this 17th day of July, 2015.

s/Clay D. Land

CLAY D. LAND

CHIEF U.S. DISTRICT COURT JUDGE
MIDDLE DISTRICT OF GEORGIA